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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,532	08/24/2001	Michael Damm	103832-401-NP	2488

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EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,532	DAMM ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5* is/are allowed.

6)☒ Claim(s) *6,7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment file 6-18-03 has been entered in part. The amendment to the claims, amending claims 1-7 and 9, and adding claims 10-12 have been entered. However, the amendment to the specification has not been entered. Applicant is reminded, that the MPEP states "[a]fter March 1, 2001, all amendments to the specification, including the claims, must be made by replacement paragraph/section/claim in clean form." The amendment to the specification was not in the proper format as required by the MPEP. See MPEP 714.

1. Acknowledgement is made with regards to the explanation of the references. However, a list of citation is needed since the on the previous list, the references were cross out. Applicants are requested to submit a 1449 for those reference not considered in the previous office action.

Maintained Rejections

1. All rejection made in the previous office action and not cited herein are hereby withdrawn.
2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 6-7 and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Engel et al.

The claims are drawn to a pharmaceutical formulation of a peptide and a carrier and method of using said peptide composition.

Note that the

Applicants argue that the claims have been amended of this application are directed to the composition made by the method of claim 1. Applicants state properties of the composition are highly dependent upon the steps of the method of claim 1. Applicants make reference the activity associated between the composition claimed in the instant claims and the one disclosed in the prior art. Applicants state that "the animal studies of Engel et al. are not predictive of Applicants' result in humans."

Applicant's arguments filed 6-18-03 have been fully considered but they are not persuasive. As stated in the previous office action, MPEP states:

> "'even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.'" MPEP 2113.

The MPEP further states that the

> "Patent Office bears a *lesser burden* of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the *burden shifts to applicant to come forward with evidence* establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)."

Applicants have not met their burden to sufficiently establish that composition of the claimed invention sufficiently different in activity than the one disclosed by the reference. The fact that the studies of the prior art were conducted only in animals is not dispositive that the composition would behave the same in humans. Applicants have not met the burden of illustrating that compositions

claimed and those of the prior art, although are the same acetate salt form, have different activity when compared side by side. Applicants have forwarded no "evidence" that the two final products, obtained by different methods, have different pharmacological activities.

Rejection is maintained.

New Grounds For Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Engel et al.

The claims are drawn to a method of treating benign prostate hyperplasia with cetrorelix.

The reference teachesa regime for therapeutic management of a benign prostatic hyperplasia and prostatic cancer employs Cetrorelix alone or in combination with .alpha.-reductase inhibitors or .alpha.-receptor blocking agents. The regimen reduces the volume of the prostate and avoids the side effects associated with testosterone levels being in a castration range. Cetrorelix is administered at dosages between 0,5 mg/day and 20 mg/week or about 0.014 mg/kg body weight per day to 0,30 mg/kg body weight per week or at levels of about 25 to 120 mg of Cetrorelix per month or 0.376 mg/kg to 1.71 mg/kg per month. (see abstract and claims). Although the reference does not teach the process by which Cetrorelix is made, the MPEP states: "'even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.'" MPEP 2113. Thus, the product obtained in Engel et al., although produced by a different method would yield the same therapeutic effect.

Allowable Subject Matter

2. Claim 1-5 are allowed.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta 9/17/05

BRENDA BRUMBACK
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